

REMARKS

The Examiner objected to claim 9 for depending on a canceled claim. Claim 9 has been amended to depend from claim 4.

In the Office Action, the Examiner rejected Claims 1, 2, 4, 6-13, 15 and 16 under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent No. 6,146,396 to Konya et al. and U.S. Patent No. 6,425,909 to Dieck, et al.

The Konya patent is directed to a declotting device. As described throughout the patent, it applies a force against the wall to remove clots:

Using the apparatus with a changing diameter, taking advantage of the strong and continuously controllable wall contact between the device and the graft wall, plus utilizing the dilation capacity of the device, the intragraft stenosis(es) can be macerated and dislodged (col. 14, lines 21-25).

The apparatus may be used instead of a dilatation balloon dilation catheter to treat short stenoses within the vasculature (col. 15, lines 7-10).

Removal of the arterial plug may be accomplished using the device in a manner similar to a Fogarty embolectomy balloon (col. 15, lines 33-35).

Consequently, Konya does not teach or suggest a distal protection device performing a filtering function, i.e. capturing embolic material dislodged by a treatment device as recited in claim 1. Furthermore, one of ordinary skill looking to design an atrumatic distal protection device to capture embolic material dislodged during a surgical procedure by another device, such as a dilatation balloon, would not look to an aggressive device designed to dislodge clot which would include aggressive back and forth movement of the device against the wall to dislodge the clot. The device of the present invention is designed to capture clots which may undesirably become dislodged; Konya is actually designed to dislodge the clots.

Second, claim 1 as amended recites the first and second slots are formed in the sidewall of the cylindrical wall extending parallel to the longitudinal axis. The slots of claim 1 are positioned proximal of the distal end of the catheter to form first and second openings in the

sidewall and are spaced apart radially and separated by a portion of the sidewall extending along the longitudinal axis. In the retracted position, the flexible member is within the openings. Thus, it is protected in the retracted position.

In contrast, in the embodiment of Figure 5 of Konya referred to by the Examiner, the deformable members are moved by adjusting the distance of portions 22 and 24. This is achieved by sliding catheter 12 relative to member 14. Clips 32 and 34 secure the plurality of deformable members and are coupled to the catheter such as by crimping or other means (see col. 9, lines 55-60). Konya does not have first and second slots in the sidewall as defined in claim 1. Konya has a 360 degree gap between clips 32, in which the deformable members are positioned. The entire region where the loops are positioned is removed. The members and jacket are therefore not protected in the retracted position.

The Dieck patent does not satisfy the deficiencies of Konya, lacking, e.g. the two slots in the sidewall as defined in claim 1 and protected retracted position. Therefore, assuming solely for the sake of argument that these patents were combined as the Examiner suggests, the recitations of claim 1 would still not be met. Consequently, for at least these reasons, the rejection of claim 1 should be withdrawn. Claims 2, 4, and 6-11 depend from claim 1 and therefore are believed patentable for at least the same reasons as claim 1.

Note that dependent claim 8 has been amended to recite that one loop is positioned distally of the other loop along the longitudinal axis. This feature is not shown in the symmetrically positioned loops of Konya as the loops lie in the same position along the longitudinal axis. (See also new dependent claims 19 and 20).

Claim 12 recites a distal protection device comprising a catheter having first and second slots extending parallel to a longitudinal axis of the device and forming first and second openings in a portion of a sidewall spaced proximally from the distal end of the sidewall. The first and second openings are spaced apart radially and separated by a portion of the sidewall. A single flexible wire is positioned within the catheter and movable from a first position having a lower profile for insertion of the catheter to a second position extending laterally from the catheter and through the sidewall, wherein in the second position the single wire forms first and second loops extending laterally such that a first end of the wire extends in a proximal direction and a second end of the wire extends in a distal direction with the loops therebetween each having an opening extending in a proximal to distal direction. Filtering material is disposed over at least a portion of the wire and is movable from a collapsed position to an expanded position in

response to movement of the wire, wherein at least a portion of the filtering material is retracted within the catheter and unexposed during insertion of the catheter. The filtering material in the expanded position allows blood flow therethrough while capturing embolic material dislodged by a treatment device.

Konya does not teach or suggest 1) the sidewall configuration with slots forming radially spaced openings separated by a portion of the sidewall, 2) a distal protection device to capture embolic material dislodged by a treatment device; 3) at least a portion of the filtering material being retracted within the catheter and unexposed during insertion of the catheter. Konya has a 360 degree gap and is designed to remove clots as discussed above with respect to claim 1. Further, since it has a 360 degree opening, the members 30 and jacket are exposed during insertion and thus could get tangled or damaged during insertion. Dieck does not cure the deficiencies of claim 12 as Dieck lacks the sidewall slots and the retraction for protection during insertion as mentioned above. Therefore, for at least these reasons, the rejection of claim 12 should be withdrawn. Claim 13 depends from claim 12 and therefore is believed patentable for at least the same reasons as claim 12.

Claim 15 recites a distal protection device comprising a catheter and a flexible member positioned and movable from a first position to a second looped position extending laterally with respect to the catheter, such that in the second looped position a loop opening is formed lying in a plane that is non-aligned with a longitudinal axis of the catheter. The flexible member is movable between the first and second positions by user control, and the filter material is movable from a collapsed position to an expanded position in response to movement of the flexible member, wherein the filter material automatically moves from the expanded position to the collapsed position upon movement of the flexible member back to the first position. Claim 15 further recites the filtering material in the expanded position allows blood therethrough while capturing material dislodged by a treatment device, and in the first position, at least a portion of the flexible member is retracted within the catheter and unexposed.

The Konya patent does not teach or suggest these features. In Figure 5 of Konya, movement of portions 22 and 24 expand and contract deformable members which in turn moves jacket 16 which covers the deformable members. In contrast, in the invention recited in claim 15, the filter material automatically moves from its stretched position to the original collapsed position when the wire is retracted. The advantages of this feature are explained on page 11 of Applicants' specification which avoids the need for insertion of a separate device over the

membrane to cover it for removal. Additionally, Konya is not a filtering device as recited in amended claim 15. Moreover, it is not retracted and unexposed as explained above with respect to claims 1 and 12. Dieck does not cure the deficiencies of Konya for the reasons discussed above. Consequently claim 15 is believed patentable over Konya and the rejection should be withdrawn.

Claim 16 depends from claim 15 and is therefore believed patentable for at least the same reasons as claim 15.

Prompt and favorable reconsideration of the present application is respectfully requested. The Examiner is invited to contact the undersigned should the Examiner believe it would expedite prosecution.

Respectfully submitted,

Dated: 11/29/07

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